

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40372

MICROBIOLOGY REVIEW

121

OFFICE OF GENERIC DRUGS, HFD-600

Microbiology Review #1

March 3, 2000

- A. 1. **ANDA:** 40-372
- APPLICANT:** Abbott Laboratories
D-389, Building AP30
200 Abbott Park Road
Abbott Park, IL 60064
2. **PRODUCT NAME:** Promethazine Hydrochloride Injection USP
3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:** 25 mg/mL or 50 mg/mL as a 1-mL fill in 2-mL single-dose Carpuject® cartridge; Intravenous injection
4. **METHOD OF STERILIZATION:**
5. **PHARMACOLOGICAL CATEGORY:** Antihistamine
- B. 1. **DATE OF INITIAL SUBMISSION:** May 28, 1999
Subject of this review (Received June 1, 1999)
2. **DATE OF AMENDMENT:** No amendments related to sterility assurance
3. **RELATED DOCUMENTS:**
DMF
DMF
DMF
DMF
4. **ASSIGNED FOR REVIEW:** February 22, 2000
- C. **REMARKS:** The subject drug is filled on the _____ (Room 250) or the _____ (Room 246) at the Abbott facility (formerly Sanofi Winthrop) in McPherson, Kansas.

- D. CONCLUSIONS: The submission is **not recommended** for approval on the basis of sterility assurance. Specific comments regarding the process are provided in "E. Review Notes" and "Microbiology Comments to be Provided to the Applicant" found at the end of this review. The deficiencies noted represent a **Minor Amendment**.

PS 3/3/2000
Paul C. DeLeo, Ph. D.

(C8H) 3/3/00

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Micro Review #1

OFFICE OF GENERIC DRUGS, HFD-620

Microbiology Review #2

April 18, 2000

- A. 1. ANDA: 40-372
- APPLICANT: Abbott Laboratories
D-389, Building AP30
200 Abbott Park Road
Abbott Park, IL 60064
2. PRODUCT NAME: Promethazine Hydrochloride Injection USP
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 25 mg/mL or 50 mg/mL as a 1-mL fill in 2-mL Carpuject® cartridge; Intravenous injection
4. METHOD OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY: Antihistamine
- B. 1. DATE OF INITIAL SUBMISSION: May 28, 1999 (Received June 1, 1999)
2. DATE OF AMENDMENT: April 14, 2000 (Received April 17, 2000)
- SUBJECT OF THIS REVIEW**
3. RELATED DOCUMENTS:
DMF
DMF
DMF
DMF
4. ASSIGNED FOR REVIEW: April 18, 2000
- C. REMARKS: The subject drug is filled on the _____ (Room 250) or the _____ (Room 246) at the Abbott facility (formerly Sanofi Winthrop) in McPherson, Kansas.
- D. CONCLUSIONS: The submission is **recommended** for approval on the basis of sterility assurance. Specific comments regarding the process are provided in "E. Review Notes".

/s/ 4/21/2000
Paul C. DeLeo, Ph. D.

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micro Review #2